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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,642	10/01/1999	GILBERT BLAISE	ML/12482.11	6239

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[REDACTED] EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/402,642	Applicant(s) Blaise et al.
	Examiner Joseph Weiss
	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Mar 15, 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-16 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

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DETAILED ACTION

Priority

1. There are multiple priority documents (the two Canadian References from which ultimate priority flows) with almost a one year separation between them, the examiner requests that applicant identify the subject matter in the claims which has the benefit of each of the respective filing dates in order to properly apply the prior art.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The amended claims are claiming non-statutory subject matter, a human being's pulmonary system.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claims 1 & 9 recites the limitation "the delivery" in line 1 of the claims. There is insufficient antecedent basis for this limitation in the claim.
7. Claims 1 & 9 recites the limitation "the patient respiratory system" is indefinite since it is claiming an patient's pulmonary system.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371C of this title before the invention thereof by the applicant for patent.

9. Claims 1-3 & 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Bathe et al (5558083).

In regards to claims 1 & 9, Bathe discloses an injection system comprising a control unit (56), a valve assembly (valves 14, 20 & 24) which includes a valve and valve actuating means which allows for variable opening of the valve (24 & 24/72 interface), said valve actuating means being coupled to said control unit, a flow meter (46) for measuring inspiratory gas flow and being coupled to said control unit (60) to provide inspiratory gas flow data; wherein the control unit controls the valve assembly so that the variable opening of the valve is responsive to inspiratory gas flow in a conduit of a ventilator to achieve a predetermined concentration of the gaseous substance and the concentration may vary from injection to injection.

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In regards to claims 2 & 10, the variable opening of the valve is proportionally responsive to the inspiratory gas flow in the conduit.

In regards to claims 3 & 11, the control unit opens the valve in response to the inspiratory gas flow when the flow exceeds a threshold indicative of an inspiratory effort and thus insures that gas is delivered only when the patient is in an inspiratory phase.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 4-7 & 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bathe in view of Dietz (5074299).

In regards to claims 4 & 5 Bathe substantially discloses the instant application's claimed invention, but does not explicitly disclose an alarm that is actuated by detection of time in between inspirations in excess of predetermined thresholds or when a single inspiration phase exceeds a predetermined threshold. However, Dietz disclose such (col. 10, line 57- col. 11 line 15). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Dietz and used them with the device of Bathe. The suggestion/motivation for doing so would have been to insure the user received the

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proper dosage of gasses. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claims 6 & 14, the suggested device discloses a control unit which can deactivate the injector based upon values received from monitoring user/device conditions which would be indicative of a improper or "alarm".

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claims 7 & 15, Bathe discloses the use of a user input device (58) configured to receive inputs from a user and it is old an well known that such devices can incorporate data displays to a user.

Response to Arguments

12. Applicant's arguments filed 15 Mar 02 have been fully considered but they are not persuasive. In response to applicant's argument that the intended result of variance of gas concentration delivered in each inspiratory cycle, a recitation of the intended use/result of the

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claimed invention **must result in a structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. **If the prior art structure is capable of performing the intended use/result, then it meets the claim.** In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claiming intended results do not serve as a structural element in device claims.

In regards to applicant's assertion that "unexplained" amendments were made for non-statutory purposes is unnecessary, the amendments regarding the pulmonary system were in response to 35 USC 112, albeit they did not resolve any issue of definiteness, but actually created a new statutory rejection under 35 USC 101. The other amendment was for resolving an objection to the claims. There are no "unexplained" amendments. However, the amendment did not fully respond to all the issues in the prior rejection applicant is reminded of his duties under 37 CFR 1.111 when responding to an office action. Failure to do so in the future will result in a finding of non-responsiveness.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, John G. Weiss, can be reached at telephone number (703) 308-2702. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



Aaron J. Lewis
Primary Examiner



Joseph F. Weiss

May 20, 2002